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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,329	01/29/2004	Sean D. Monahan	Mirus.041.01	6227
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25032                      7590                      07/02/2007  
MIRUS CORPORATION  
505 SOUTH ROSA RD  
MADISON, WI 53719

EXAMINER
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BARHAM, BETHANY P

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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07/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/767,329	<b>Applicant(s)</b> MONAHAN ET AL.	
	<b>Examiner</b> Bethany P. Barham	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 22 May 2007.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-8 and 21-24 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-8 and 21-24 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Summary*

#### **REQUEST FOR CONTINUED EXAMINATION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/22/2007 has been entered. Claims 1-8 and 21-24 are pending in this action. Claims 1-8 and 21-24 are rejected.

#### **MAINTAINED REJECTIONS**

##### ***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0335133 A2 ('133) as evidenced by US 5,939,536 ('536).

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'133 disclose compositions comprising surfactant proteins and phospholipids (abstract). Said protein-based compositions may be attached to a lipid via a non-covalent or covalent bond (page 3, lines 24-27 and page 4, lines 7-18). The compositions contain cell-targeting signals, as they are capable of delivering of the protein/lipid complex to the lungs (page 3, lines 12-13). It is the examiner's position that the surfactant vesicles used to transport proteins to the lungs are liposomes (page 3, lines 24-27).

According to '133, one type of phospholipid suitable for use in the surfactant protein/phospholipids mixture is phosphatidylcholine (page 2, lines 15-26). As evidenced by '536, phosphatidylcholines are known to be used as detergents (column 4, lines 8-25). Depending on the "R" groups attached to phosphatidylcholine, said phosphatidylcholine can comprise a hydrophobic alkyl chain of 4 to 30 carbons. Thus, like the instant claim 1, '133 disclose a detergent/polypeptide complex.

In terms of the process of preparing said lipid/peptide complex, leuprolide, a nanopeptide, was admixed with lipids, phospholipids, and detergents (page 5, line 15-25). The solvents were then evaporated (page 5, lines 20-23). It is the examiner's position that, after evaporation of the solvents, the peptide/lipid complex was dried. After the solvent was evaporated from the peptide/lipid complex, a small quantity of ethanol, an aqueous solvent, was added to the complex (page 5, lines 20-23). After the preparation of said lipid/peptide complex, the dispersion was administered to a subject (page 6, lines 15-29). Specifically, the drug complex was delivered to dogs via a catheter (page 6, lines 28-29). Since the drug complex was administered to dogs via the

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"permanent stoma near the bifurcation of the major bronchi," the examiner respectfully submits that cells were necessarily "contacted" with the drug complex.

The claims are therefore anticipated by EP 0335133 A2 ('133) as evidenced by US 5,939,536 ('536).

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,858,398 ('398) as evidenced by US 3,578,591 ('591).

'398 disclose pharmaceutical compositions comprising (1) phospholipids, (2) surfactants, (3) sterols, (4) pharmaceutically active agents, and (5) fatty acids having a chain length of C1 to C14 (Claim 1). According to '398, proteins, such as insulin, may be used as the active agent and surfactants, such as sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate, may be used in the composition (Claims 1-2 and Example 1). As evidenced by '591, sorbitan monooleate, sorbitan sesquileate, and sorbitan monolaurate are all suitable detergents (column 6, lines 26-40). Like the instant claim set, the polypeptide complex advanced by '398 may be noncovalently bound and may be in "dry" form (column 12, lines 56; column 19, line 65 - column 20, line 5; and column 20, line 48). Sterol-based compounds are also added to the composition in order to increase the compositions "adherence to absorptive cells" (column 15, lines 35-54). '398 also set forth a process for making and using the above composition (Example 1, column 19, line 11 - column 20, line 52). According to '398, an insulin peptide may be combined with phospholipids, sterols, and surfactants (including the above detergents) and said complex may be dissolved in an organic solvent (Example 1). The polypeptide

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complex may then be dried (column 19, line 65- column 20, line 5 and Example 3). After preparing the polypeptide-complex, said complex can be dissolved in a suitable solvent and contacted with cells (column 26, lines 25 - column 27, line 60).

The claims are therefore anticipated by US 5,858,398 ('398) as evidenced by US 3,578,591 ('591).

### ***Response to Arguments***

Applicant's arguments filed 05/22/2007 have been fully considered but they are not persuasive. Applicants have argued that they are entitled to the generic limitation of dried noncovalently associated polypeptide/surfactant complexes wherein the surfactant consists of a detergent; the above rejections meet these limitations as they too are directed to intracellular delivery of an identical complex to that as claimed in the instant application. The examiner respectfully submits that because the compositions are the same, the rejections stand.

Furthermore, Applicant's argue and submit structures showing that alpha-lyso phosphatidylcholine and phosphatidylcholine are structurally different. The Examiner respectfully points out that phosphatidylcholines in general are detergents according to the broadest interpretation of applicant's definition of detergent which states: "detergents are compounds that are soluble in water and cause nonpolar substances to go into solution in water...[and] have both hydrophobic and hydrophilic groups." (page 14, lines 3-5). The rejection of record is made against EP 0335133 as evidenced by US 5,939,536 and the '536 is used to show that various phosphatidylcholines are known

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detergents and that in literature the 'use of phosphatidylcholine detergents' is known (column 4, lines 24-30).

Applicants argue that their invention is a composition consisting essentially of a charged polypeptide and detergent of opposite charge, while '398 as evidenced by '591 teaches only a composition comprising a pharmaceutical agent, water soluble phospholipid, lipid soluble phospholipid, non-ionic detergent (HLB 15 or less), non-ionic detergent (HLB 6 or less) and water soluble sterol. However, the examiner respectfully points out that sterols are known lipids (instant claim 4), and that the pharmaceutical agent insulin is a protein and that the remaining ingredients, as shown above are phospholipids and surfactants or further detergents as claimed in the instant application. The instant claims are so generic that any polypeptide-surfactant complex can be made and '398 as evidenced by '591 makes a composition comprising only polypeptides and surfactants, and further a lipid which reads on the instant claim set. As such the rejections are hereby maintained.

### ***Conclusion***

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B.P. Barham  
Examiner-1615

  
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